UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
	)	Dkt. No. 1:13-md-2419-RWZ
This Document Relates to:	)	
Suits naming Saint Thomas Outpatient Neurosurgical Center, LLC	)	

SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC, HOWELL ALLEN CLINIC, A PROFESSIONAL CORPORATION, JOHN W. CULCLASURE, MD, AND DEBRA V. SCHAMBERG, RN, CNOR'S RESPONSES TO THE PLAINTIFFS' STEERING COMMITTEE'S FIRST SET OF REQUESTS FOR ADMISSIONS AND CORRESPONDING INTERROGATORY

Pursuant to Rules 26, 33, and 36 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"), Howell Allen Clinic, a Professional Corporation ("Howell Allen"), John W. Culclasure, MD ("Dr. Culclasure"), and Debra V. Schamberg, RN, CNOR ("Ms. Schamberg") (collectively, "these Defendants") provide the following responses to the Plaintiffs' Steering Committee's First Set of Requests for Admissions and Corresponding Interrogatory.

INTERROGATORY

1. If your response to any of the following Requests for Admission is other than an unqualified admission, for each such Request for Admission state all facts (not opinions) that you contend support in any manner your refusal to admit or your qualification of your admission, identify all documents, notes, reports, memoranda, electronic and/or tape recordings, photographs, oral statements, or any other tangible or intangible thing that supports in any manner your refusal to admit or your qualification of your admission, the name and address of the custodian of all tangible things identified above, and the name and address of all persons, including consultants and experts, purporting to have knowledge or factual data upon which you base your refusal to admit or the qualification of your admission.

RESPONSE:

Objection. This Interrogatory is overbroad, unduly burdensome, seeks the disclosure of expert opinions before the Court has set a schedule for such disclosures, seeks information that is irrelevant, not reasonably calculated to lead to the discovery of admissible evidence, and seeks information that is privileged from discovery by attorney-client privilege, the work-product doctrine, and the Tennessee Peer Review Law of 1967, Tenn. Code Ann. § 63-6-219 and/or the Tennessee Patient Safety and Quality Improvement Act of 2011, Tenn. Code Ann. §§ 63-1-150, 68-11-272.

Subject to and without waiving said objections, in response to this Interrogatory, these Defendants have incorporated into any denials or qualifications of these Requests for Admissions the basis or reason for the denial or qualification. Where the Response does not directly refer to non-privileged documents relied upon in making the denial or qualification, the Response provides a citation to the relevant supporting documentation.

REQUESTS FOR ADMISSIONS

1. Admit that in 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report stated that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination." A copy of that published report is attached as Exhibit 1.

RESPONSE:

These Defendants admit that the United States Centers for Disease Control ("CDC") published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections in 2002 and that the "Editorial Note" section states that "[p]urchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that is licensed in their state and that follows appropriate measures to ensure that injectable products are free of contamination." These Defendants deny that this is the entirety of the publication. These Defendants object, under Federal Rule of Evidence 106, to the admission of this limited excerpt from the CDC publication. These Defendants admit that Exhibit 1 appears to be a true and correct copy of the report referenced in Request for Admission #1.

2. Admit that Exhibit 1 is "a record or statement of a public office" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. Roughly half of the authors are private and public university professors, physicians, and researchers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

3. Admit that Exhibit 1 sets out "factual findings from a legally authorized investigation" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. Roughly half of the authors are private and public university professors, physicians, and researchers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

4. Admit that Exhibit 1's source of information does not "indicate a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. Roughly half of the authors are private and public university professors, physicians, and researchers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

5. Admit that, as to Exhibit 1, no other circumstance "indicate[s] a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. Roughly half of the authors are private and public university professors, physicians, and researchers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

6. Admit that on March 24, 2005, USA Today published a front page article with the following headline: **"Safety concerns grow over pharmacy-mixed drugs."** A true and correct copy of the text from that article is attached as Exhibit 2.

RESPONSE:

These Defendants admit that USA Today published an article titled "Safety concerns grow over pharmacy-mixed drugs." These Defendants insist that Federal Rule of Evidence 106 requires that the recipient of this Response also be informed that article also notes that (1) "regulators have long allowed [compounding] because 'the vast majority of pharmacies . . . provide a valuable medical service,'" (2) "proponents say compounding pharmacies overall are safe," (3) "several states are tightening their rules overseeing firms that compound drugs," and (4) "the FDA has stepped in when it decides a pharmacy has crossed the line and become a drug manufacturer." Based on information known or readily attainable, and after making reasonable inquiry, these Defendants lack sufficient information to admit or deny that the article was a front page story. These Defendants admit that Exhibit 2 appears to be a true and correct copy of the article referenced in Request for Admission #6.

7. Admit that in 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey stated "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths." A true and correct copy of the FDA's report titled *2006 Limited FDA Survey of Compounded Drug Products* is attached as Exhibit 3.

RESPONSE:

These Defendants admit that the FDA reported conducting a survey of compounded drug products in 2006. These Defendants admit that the study reported that the FDA collected 73 finished drug products from compounding pharmacies across the country during unannounced visits, but the FDA excluded 37 of the samples from the study because they were deemed unusable for various reasons. These Defendants admit that the study reported that, of the 36 samples tested, 12 (33%) failed analytic testing, but note under Federal Rule of Evidence 106, that "[m]ost of the products that failed analysis did so due to sub or super-potency . . . or a lack of uniformity of individual dosage units." These Defendants affirmatively state that the FDA did not test for sterility and that the study indicates that "[t]he majority of the finished compounded product samples analyzed in th[e] survey were hormone therapy products." The article also states that the "FDA has long recognized that traditional pharmacy compounding serves an important public health function." These Defendants admit that Exhibit 3 appears to be a true and correct copy of the report titled *2006 Limited FDA Survey of Compounded Drug Products*.

8. Admit that Exhibit 3 is "a record or statement of a public office" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied in part. The article draws conclusions regarding sterility and contamination from articles in medical journals that were written by non-governmental employees. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees and is not a means to admit otherwise inadmissible hearsay medical journal articles. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993). References to issues with contamination and sterility are inferred and cited from inadmissible medical journal articles, which do not meet the public records exception of Federal Rule of Evidence 803(8). To the extent that the survey does not rely upon or draw conclusions from medical journal articles, it meets the hearsay exception codified at Federal Rule of Evidence 803(8).

9. Admit that Exhibit 3 sets out "factual findings from a legally authorized investigation" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied in part. The article draws conclusions regarding sterility and contamination from articles in medical journals that were written by non-governmental employees. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees and is not a means to admit otherwise inadmissible hearsay medical journal articles. *See Toole v. McClintock,* 999 F.2d 1430, 1435 (11th Cir. 1993). References to issues with contamination and sterility are inferred and cited from inadmissible medical journal articles, which do not meet the public records exception of Federal Rule of Evidence 803(8). To the extent that the survey does not rely upon or draw conclusions from medical journal articles, it meets the hearsay exception codified at Federal Rule of Evidence 803(8).

10. Admit that Exhibit 3's source of information does not "indicate a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied in part. The article draws conclusions regarding sterility and contamination from articles in medical journals that were written by non-governmental employees. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees and is not a means to admit otherwise inadmissible hearsay medical journal articles. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993). References to issues with contamination and sterility are inferred and cited from inadmissible medical journal articles, which do not meet the public records exception of Federal Rule of Evidence 803(8). To the extent that the survey does not rely upon, cite, or draw conclusions from medical journal articles, it meets the hearsay exception codified at Federal Rule of Evidence 803(8).

11. Admit that, as to Exhibit 3, no other circumstance "indicate[s] a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied in part. The article draws conclusions regarding sterility and contamination from articles in medical journals that were written by non-governmental employees. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees and is not a means to admit otherwise inadmissible hearsay medical journal articles. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993). References to issues with contamination and sterility are inferred and cited from inadmissible medical journal articles, which do not meet the public records exception of Federal Rule of Evidence 803(8). To the extent that the survey does not rely upon or draw conclusions from medical journal articles, it meets the hearsay exception codified at Federal Rule of Evidence 803(8).

12. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." A true and correct copy of that article is attached as Exhibit 4.

RESPONSE:

These Defendants admit that the FDA published an article titled "The Special Risks of Pharmacy Compounding" in May 2007. These Defendants admit that Exhibit 4 appears to be a true and correct copy of the report referenced in Request for Admission #12.

13. Admit that Exhibit 4 is "a record or statement of a public office" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not (1) drafted pursuant to a legally authorized investigation, (2) a final agency action, or (3) a binding document upon the FDA. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); 21 C.F.R. § 10.85(k) ("[a] statement or advice given by an FDA employee. . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

14. Admit that Exhibit 4 sets out "factual findings from a legally authorized investigation" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not (1) drafted pursuant to a legally authorized investigation, (2) a final agency action, or (3) a binding document upon the FDA. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); 21 C.F.R. § 10.85(k) ("[a] statement or advice given by an FDA employee. . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler*, 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan*, 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

15. Admit that Exhibit 4's source of information does not "indicate a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not (1) drafted pursuant to a legally authorized investigation, (2) a final agency action, or (3) a binding document upon the FDA. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); 21 C.F.R. § 10.85(k) ("[a] statement or advice given by an FDA employee. . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman, 1*50 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

16. Admit that, as to Exhibit 4, no other circumstance "indicate[s] a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not (1) drafted pursuant to a legally authorized investigation, (2) a final agency action, or (3) a binding document upon the FDA. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); 21 C.F.R. § 10.85(k) ("[a] statement or advice given by an FDA employee. . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman, 1*50 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

17. Admit that in 2010, the FDA posted an educational video on YouTube regarding compounded drugs. That educational video is found on the World Wide Web at http://www.youtube.com/watch?v=kif_rmtIQb0.

RESPONSE:

These Defendants admit that the FDA posted an educational video on YouTube in 2010 regarding concerns over the quality of compounded drugs.

18. Admit that on November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (*e.g.*, United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
>
> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

An excerpt from that joint report is attached as Exhibit 5.

RESPONSE:

These Defendants admit that the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP"), and other medical societies published a joint report regarding drug shortages, and that the report included an article written by the ASHP with the quote included in Request for Admission #18. These Defendants deny this is the entire report or that it applies to them.

These Defendants admit that Exhibit 5 is a nine (9) page excerpt from the 52 page report. These Defendants object to introduction of excerpts from a nine (9) page document embedded in a 52 page report pursuant to Federal Rule of Evidence 106. These Defendants deny that the report was published on November 5, 2010. The report was created for a Drug Shortages Summit that occurred on November 5, 2010, but the report was not published until on or about January 10, 2011.[1]

[1] http://www.asahq.org/For-Members/Advocacy/Washington-Alerts/Drug-Shortages-Summit-Summary-Released.aspx.

19. Admit that on [sic] May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products." Portions of that report are attached as Exhibit 6.

RESPONSE:

These Defendants admit that the CDC published a report in May 2012 regarding fungal infections arising from medications obtained from a compounding pharmacy and that the report states that "contamination of compounded sterile preparations has caused outbreaks." The article noted that, in 22 years, the "FDA has learned of approximately 200 adverse events associated with 71 compounded products." The report further states that "[c]ompounded sterile preparations must be prepared according to aseptic practices recommended by organizations such as the United States Pharmacopeia, as stated in United States Pharmacopeia-National Formulary (3)" These Defendants affirmatively state that NECC represented that it complied with the relevant standards of the United States Pharmacopeia. These Defendants admit that Exhibit 6 appears to be a true and correct copy of the report referenced in Request for Admission #19. These Defendants deny that this is the entirety of the publication. These Defendants object, under Federal Rule of Evidence 106, to the admission of this limited excerpt from the CDC publication.

20. Admit that Exhibit 6 is "a record or statement of a public office" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. At least three of the authors are non-governmental healthcare providers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

Additionally, the article is not (1) a final agency action or (2) a binding document upon the CDC. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

21. Admit that Exhibit 6 sets out "factual findings from a legally authorized investigation" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. At least three of the authors are non-governmental healthcare providers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

Additionally, the article is not (1) a final agency action or (2) a binding document upon the CDC. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

22. Admit that Exhibit 6's source of information does not "indicate a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. At least three of the authors are non-governmental healthcare providers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

Additionally, the article is not (1) a final agency action or (2) a binding document upon the CDC. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

23. Admit that, as to Exhibit 6, no other circumstance "indicate[s] a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. At least three of the authors are non-governmental healthcare providers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

Additionally, the article is not (1) a final agency action or (2) a binding document upon the CDC. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

24. Admit that in 2010, the American Society of Health System Pharmacists published the "ASHP Guidelines on Outsourcing Sterile Compounding Services." A true and correct copy of that publication is attached as Exhibit 7.

RESPONSE:

These Defendants admit that Exhibit 7 appears to be a true and correct copy of the guidelines referenced in Request to Admit #24 but deny that the guidelines apply to them. The guidelines were developed to assist health care organizations in deciding whether to outsource sterile pharmacy compounding performed within a hospital.

25. Admit that the American Society of Health System Pharmacists developed a "Contractor Assessment Tool" for healthcare organizations to use in conjunction with assessing compounding pharmacies. A true and correct copy of that assessment tool is attached as Exhibit 8.

RESPONSE:

Denied. The "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" was developed by the ASHP Foundation and PharMEDium Services, LLC for health-system pharmacy departments that choose to outsource the preparation of sterile parenteral medications.[2] Based on information known or readily attainable, and after making reasonable inquiry, these Defendants lack sufficient information to admit or deny that the "Contractor Assessment Tool" was developed for use "in conjunction with assessing compounding pharmacies." These Defendants admit that Exhibit 8 appears to be a true and correct copy of the document referenced in Request for Admission # 25 but deny that it applies to them.

26. Admit that in December 2011, the International Academy of Compounding Pharmacists published the "Compounding Pharmacy Assessment Questionnaire." A true and correct copy of that questionnaire is attached as Exhibit 9.

RESPONSE:

Denied as stated. The IACP published the "Compounding Pharmacy Assessment Questionnaire" in October 2011, not December.[3] Additionally, these Defendants affirmatively state that the questionnaire is designed to obtain a representation by the compounder of compliance with United States Pharmacopeia (USP) standards with which NECC represented that it complied.[4] These Defendants admit that Exhibit 9 appears to be a true and correct copy of the questionnaire referenced in Request for Admission # 26.

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[2] http://www.ashpfoundation.org/sterileproductstool

[3] http://www.iacprx.org/associations/13421/files/IACP%20Press%20Release%20CPAQ%20Tool%20Announcement%2010052011.pdf

[4] *Id.*

27. Admit that NECC operated a compounding pharmacy in Framingham, Massachusetts on a site shared with a mattress recycling and/or garbage compacting operation.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that NECC operated a compounding pharmacy in Framingham, Massachusetts on a site shared with a mattress recycling and/or garbage compacting operation.

28. Admit that NECC compounded MPA in so-called "clean rooms" that were filthy.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that NECC compounded methylprednisolone acetate ("MPA") in cleanrooms that were "filthy."

29. Admit that a leaky boiler stood in a pool of stagnant, dirty water at NECC's compounding facility.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that a leaky boiler stood in a pool of stagnant, dirty water at NECC's compounding facility.

30. Admit that the autoclaves used to sterilize products at NECC were discolored, tarnished, and contained visible moisture.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that the autoclaves used to sterilize products at NECC were discolored, tarnished, and contained visible moisture.

31. Admit that the air vents in the NECC "clean" rooms were covered with dirt and white fuzz.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that the air vents in the NECC "clean" rooms were covered with dirt and white fuzz.

32. Admit that the metal shelf in the "clean" room used to prepare MPA was covered in a reddish-brown, cloudy substance.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that the metal shelf in the "clean" room used to prepare MPA was covered in a reddish-brown, cloudy substance.

33. Admit that Howell Allen Clinic is a neurosurgical group with its primary office located in Nashville, Tennessee.

RESPONSE:

Admitted.

34. Admit that Howell Allen Clinic owns a 50% interest in Saint Thomas Neurosurgical.

RESPONSE:

Admitted.

35. Admit that Saint Thomas Neurosurgical is a for-profit limited liability company.

RESPONSE:

Admitted.

36. Admit that Saint Thomas Neurosurgical's profits are distributed, in part, to Howell Allen Clinic.

RESPONSE:

These Defendants admit that STOPNC periodically makes distributions to Howell Allen.

37. Admit that Howell Allen Clinic refers patients to Saint Thomas Neurosurgical.

RESPONSE:

These Defendants admit that individual physicians at Howell Allen refer patients to STOPNC.

38. Admit that Howell Allen Clinic refers patients to Saint Thomas Neurosurgical for epidural steroid injections.

RESPONSE:

These Defendants admit that individual physicians at Howell Allen refer patients to STOPNC for epidural steroid injections.

39. Admit that Saint Thomas Neurosurgical administers epidural steroid injections to patients for profit.

RESPONSE:

Denied as stated. Physicians at STOPNC administer epidural steroid injections as a healthcare service provided for the intended benefit of patients. These Defendants admit that STOPNC is a for-profit limited liability company.

40. Admit that when Saint Thomas Neurosurgical distributes profits to Howell Allen Clinic, the owners of Howell Allen Clinic make more money.

RESPONSE:

Denied as stated. Distribution of STOPNC profits to Howell Allen does not necessarily mean that Howell Allen's owners "make more money."

41. Admit that Saint Thomas Neurosurgical is located on the 9th floor of the Medical Plaza East Building on the St. Thomas Hospital campus.

RESPONSE:

These Defendants admit that STOPNC's principal place of business is located on the 9th Floor of the Medical Plaza East office building located at 4230 Harding Pike in Nashville, Davidson County, Tennessee 37205. These Defendants are without sufficient knowledge or information, and after making reasonable inquiry, cannot admit or deny whether STOPNC is located on the "St. Thomas Hospital campus."

42. Admit that Saint Thomas Network owns a 50% interest in Saint Thomas Neurosurgical.

RESPONSE:

Admitted.

43. Admit that Saint Thomas Network is a company with no employees.

RESPONSE:

These Defendants have made a reasonable inquiry and the information known and readily obtainable is insufficient to permit an admission or denial.

44. Admit that Saint Thomas Network is owned by Saint Thomas Health, the same entity that owns St. Thomas Hospital.

RESPONSE:

These Defendants have made a reasonable inquiry and the information known and readily obtainable is insufficient to permit an admission or denial.

45. Admit that the CEO of St. Thomas Hospital is on the Board of Governors of Saint Thomas Neurosurgical.

RESPONSE:

Denied.

46. Admit that the Medical Director of St. Thomas Hospital regularly attended Saint Thomas Neurosurgical's Board of Governors meetings.

RESPONSE:

Admitted.

47. Admit that Saint Thomas Neurosurgical conducted its Board of Governors meetings in the St. Thomas Hospital board room.

RESPONSE:

Admitted.

48. Admit that John Culclasure, M.D. was the Medical Director for Saint Thomas Neurosurgical in 2012.

RESPONSE:

Admitted.

49. Admit that John Culclasure, M.D. was an agent, employee or member of Howell Allen Clinic throughout 2012.

RESPONSE:

These Defendants admit that Dr. Culclasure was an employee of Howell Allen in 2012.

50. Admit that Debra Schamberg, R.N. was the Facilities Director for Saint Thomas Neurosurgical in 2012.

RESPONSE:

These Defendants admit that Ms. Schamberg was the Facility Director of STOPNC in 2012.

51. Admit that Debra Schamberg, R.N was an agent, employee or member of Howell Allen Clinic throughout 2012.

RESPONSE:

These Defendants admit that Ms. Schamberg was an employee of Howell Allen in 2012.

52. Admit that Saint Thomas Neurosurgical's Facility Director, Debra Schamberg, R.N., is an employee of Howell Allen Clinic.

RESPONSE:

Admitted.

53. Admit that Saint Thomas Neurosurgical's Medical Director, John Culclasure, M.D. is an employee of Howell Allen Clinic.

RESPONSE:

Admitted.

54. Admit that all persons working at Saint Thomas Neurosurgical in 2012 were employees of Howell Allen Clinic.

RESPONSE:

Denied.

55. Admit that Debra Schamberg R.N. and John Culclasure, M.D. used Howell Allen Clinic email addresses in 2012.

RESPONSE:

Admitted.

56. Admit that all persons working at Saint Thomas Neurosurgical used Howell Allen Clinic email addresses in 2012.

RESPONSE:

Denied.

57. Admit that Saint Thomas Neurosurgical's Facility Director, Debra Schamberg, is part of Howell Allen Clinic's Staff.

RESPONSE:

These Defendants admit that Ms. Schamberg is an employee of Howell Allen.

58. Admit that Scott Butler is the Chief Administrative Officer and/or CEO of Howell Allen Clinic.

RESPONSE:

These Defendants admit that Scott Butler is the CAO of Howell Allen.

59. Admit that Scott Butler reported to the *Tennessean* that Saint Thomas Neurosurgical started 12 years ago as a joint venture between Saint Thomas Network and Howell Allen Clinic.

RESPONSE:

These Defendants have made a reasonable inquiry, and the information known and readily obtainable is insufficient to permit an admission or denial. Mr. Butler does not recall whether he provided this information to the *Tennessean*.

60. Admit that Scott Butler reported to the *Tennessean* that Howell Allen Clinic manages the hiring and workers at Saint Thomas Neurosurgical.

RESPONSE:

Admitted.

61. Admit that Scott Butler reported to the *Tennessean* that Saint Thomas Network handles contracting, credentialing and finances at Saint Thomas Neurosurgical.

RESPONSE:

Admitted.

62. Admit that Gregory Lanford, M.D. is the registered agent for and president of Howell Allen Clinic.

RESPONSE:

Admitted.

63. Admit that Gregory Lanford, M.D. is the registered agent for Saint Thomas Neurosurgical.

RESPONSE:

Admitted.

64. Admit that Amanda Starr is an employee of Howell Allen Clinic. She works at Howell Allen Clinic's office location at 2011 Murphy Avenue, Suite 301, Nashville, Tennessee, 37203.

RESPONSE:

Admitted.

65. Admit that Amanda Starr signed several Domestic Return Receipts for certified mail packages addressed to Gregory Lanford, M.D., registered agent for Howell Allen Clinic and Saint Thomas Neurosurgical, in connection with this litigation.

RESPONSE:

Admitted.

66. Admit that Dr. Culclasure and Ms. Schamberg co-managed Saint Thomas Neurosurgical's day-to-day operations.

RESPONSE:

These Defendants admit that Dr. Culclasure and Ms. Schamberg were both involved in the day-to-day management of STOPNC.

67. Admit that Dr. Culclasure and Ms. Schamberg were directly involved with and responsible for Saint Thomas Neurosurgical's decision to purchase MPA from NECC.

RESPONSE:

These Defendants admit that Dr. Culclasure and Ms. Schamberg were involved in and had responsibility for deciding to purchase MPA from NECC.

68. Admit that Saint Thomas Neurosurgical, Dr. Culclasure, and Ms. Schamberg made the decision to purchase MPA in bulk from NECC because it was the cheapest alternative.

RESPONSE:

Denied. Additionally, these Defendants object to this Request for Admission and the explanation required by the corresponding Interrogatory on the grounds that they are unreasonably cumulative, duplicative, and the information sought can be obtained from some other source that is more convenient, less burdensome, and less expensive. FRCP 26(b)(2)(C)(i). STOPNC has explained the decision to purchase MPA from NECC in its Responses to Interrogatories in *Reed v. STOPNC et al.*, Case No. 13C417, *May v. STOPNC, et al.*, Case No. 13C606, *Parman v. STOPNC, et al.*, Case No. 13C1005, and/or *Neely v. STOPNC, et al.*, Case No. 13C1876, Fifth Circuit Court for Davidson County, Tennessee. The Plaintiffs from these four state court actions voluntarily dismissed the suits, refiled them in federal court, and are now part of the MDL. The Plaintiffs have this information. This Request for Admission is duplicative.

69. Admit that Saint Thomas Neurosurgical did not use patient-specific individual prescriptions when buying MPA from NECC in bulk.

RESPONSE:

These Defendants admit that they provided patient names, not individual prescription slips, when ordering from NECC but deny that the standard of acceptable professional practice required them to do so.

70. Admit that Saint Thomas Neurosurgical could have purchased Depo-medrol (or the generic version of that drug) manufactured by an FDA regulated pharmaceutical manufacturer such as Pfizer or Teva for use in epidural steroid injections.

RESPONSE:

Objection. This Request for Admission is overbroad and seeks information that is not reasonably calculated to lead to the discovery of admissible evidence as it does not identify a time period during which STOPNC could have purchased MPA from "an FDA-regulated pharmaceutical manufacturer such as Pfizer or Teva for use in epidural steroid injections." These Defendants admit that STOPNC could have purchased MPA from Pfizer and/or Teva for use in epidural steroid injections at some point in time. Additionally, these Defendants affirmatively state that NECC was regulated by the FDA. Beyond that, these Defendants cannot further respond.

71. Admit that from 2000 to the present, the medication formulary for Saint Thomas Neurosurgical lists those steroids that are acceptable for use at Saint Thomas Neurosurgical and includes: Decadron, Depo-medrol, Solumedrol and Celestone Soluspan.

RESPONSE:

These Defendants admit that STOPNC's medication formulary lists Decadron, Depo-Medrol, Solumedrol, and Celestone Soluspan. These Defendants deny that those were the only steroids acceptable for use at STOPNC. These Defendants further deny that STOPNC's formulary prohibited the use of generic equivalents, such as MPA from a compounding pharmacy.

72. Admit that the Saint Thomas Neurosurgical formulary does not include generic MPA or MPA from a compounding pharmacy as acceptable for use at Saint Thomas Neurosurgical.

RESPONSE:

These Defendants admit that MPA from a compounding pharmacy is not specifically listed on STOPNC's formulary. These Defendants deny that STOPNC's formulary prohibited the use of generic equivalents, such as MPA from a compounding pharmacy.

73. Admit that the Saint Thomas Neurosurgical formulary does include and allows for the administration of MPA manufactured by Pfizer under the name Depo-medrol.

RESPONSE:

These Defendants admit that Depo-Medrol is listed on STOPNC's formulary. These Defendants deny that STOPNC's formulary prohibited the use of generic equivalents, such as MPA from a compounding pharmacy.

74. Admit that a true and correct copy of Saint Thomas Neurosurgical's written policy entitled "Formulary," as it existed in June through September of 2012, is attached as Exhibit 10.

RESPONSE:

Admitted.

75. Admit that in late 2010, Saint Thomas Neurosurgical began purchasing MPA from Clint Pharmaceuticals.

RESPONSE:

Objection. This Request for Admission seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding healthcare providers' dealings with suppliers of corticosteroids other than NECC is not discoverable. Order regarding Subpoenas and Motions to Quash [Dkt. 572]. Regardless, STOPNC has already produced (1) all communications, brochures, advertisements, etc. received from or sent to NECC; (2) various invoices, communications, and other documents from Clint Pharmaceuticals and CuraScript, Inc.; and (3) a spreadsheet identifying the supplier, quantity, vial size, and price of MPA purchased by STOPNC from 2008 to 2010, which, taken together, cover all of STOPNC's purchases of MPA from 2008 to 2012. The Plaintiffs have this information. This Request for Admission is duplicative.

Subject to and without waiving said objections, these Defendants admit that STOPNC began purchasing MPA from Clint Pharmaceuticals in December 2010.

76. Admit that the MPA that Saint Thomas Neurosurgical purchased from Clint Pharmaceuticals came from an FDA approved manufacturer.

RESPONSE:

Objection. This Request for Admission seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding healthcare providers' dealings with suppliers of corticosteroids other than NECC is not discoverable. Order regarding Subpoenas and Motions to Quash [Dkt. 572]. Regardless, STOPNC has already produced (1) all communications, brochures, advertisements, etc. received from or sent to NECC; (2) various invoices, communications, and other documents from Clint Pharmaceuticals and CuraScript, Inc.; and (3) a spreadsheet identifying the supplier, quantity, vial size, and price of MPA purchased by STOPNC from 2008 to 2010, which, taken together, cover all of STOPNC's purchases of MPA from 2008 to 2012. The Plaintiffs have this information. This Request for Admission is duplicative.

Subject to and without waiving said objections, these Defendants deny that the MPA purchased from Clint Pharmaceuticals came from an "FDA approved manufacturer." The FDA does not "approve" manufacturers. The FDA approves drugs. Manufacturers *register* with the FDA.

77. Admit that according to Clint Pharmaceuticals' website:

Clint Pharmaceuticals *has not, and never will,* distribute any products that are compounded. All products that are distributed by Clint Pharmaceuticals are from manufacturers that have acquired approval from the FDA. We have historically recommended that all providers DO NOT use unapproved compounded steroids especially when FDA approved products are commercially available.

RESPONSE:

Objection. This Request for Admission seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding healthcare providers' dealings with suppliers of corticosteroids other than NECC is not discoverable. Order regarding Subpoenas and Motions to Quash [Dkt. 572]. Regardless, STOPNC has already produced (1) all communications, brochures, advertisements, etc. received from or sent to NECC; (2) various invoices, communications, and other documents from Clint Pharmaceuticals and CuraScript, Inc.; and (3) a spreadsheet identifying the supplier, quantity, vial size, and price of MPA purchased by STOPNC from 2008 to 2010, which, taken together, cover all of STOPNC's purchases of MPA from 2008 to 2012. The Plaintiffs have this information. This Request for Admission is duplicative.

Subject to and without waiving said objections, these Defendants admit that the Clint Pharmaceuticals website *currently* contains the statement quoted in Request for Admission #77.

78. Admit that Saint Thomas Neurosurgical purchased MPA from Clint Pharmaceuticals at the price of $6.49 per 80mg vial. An invoice from Clint Pharmaceuticals dated January 26, 2011 and confirming that price is attached as Exhibit 11.

RESPONSE:

Objection. This Request for Admission seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding healthcare providers' dealings with suppliers of corticosteroids other than NECC is not discoverable. Order regarding Subpoenas and Motions to Quash [Dkt. 572]. Regardless, STOPNC has already produced (1) all communications, brochures, advertisements, etc. received from or sent to NECC; (2) various invoices, communications, and other documents from Clint Pharmaceuticals and CuraScript, Inc.; and (3) a spreadsheet identifying the supplier, quantity, vial size, and price of MPA purchased by STOPNC from 2008 to 2010, which, taken together, cover all of STOPNC's purchases of MPA from 2008 to 2012. The Plaintiffs have this information. This Request for Admission is duplicative.

Subject to and without waiving said objections, these Defendants admit that STOPNC purchased MPA from Clint Pharmaceuticals for $6.49 per vial.

79. Admit that in May 2011, an NECC sales representative emailed Saint Thomas Neurosurgical's facility director, Ms. Schamberg, asking what price NECC would need to offer for MPA in order to gain Saint Thomas Neurosurgical's business. Ms. Schamberg replied that if NECC could get the price under $6.50 per vial she would be willing to "talk" to NECC. A true and correct copy of email correspondence confirming that exchange is attached as Exhibit 12.

RESPONSE:

These Defendants admit that NECC's sales rep contacted Ms. Schamberg in approximately May 2011 to offer to supply STOPNC with MPA. In response to the sales rep's inquiry, Ms. Schamberg advised the sales rep that STOPNC would consider ordering from NECC if NECC could offer about the same price as STOPNC's current supplier, $6.49 per vial. These Defendants admit that Exhibit 12 appears to be a true and correct copy of the email exchange referenced in Request for Admission # 79.

80. Admit that on June 9, 2011, Clint Pharmaceuticals increased the price to Saint Thomas Neurosurgical for MPA from $6.49 to $8.95 per vial, an increase of $2.46 per vial. A true and correct copy of an Invoice from Clint Pharmaceuticals dated June 9, 2011 confirming that price increase is attached hereto as Exhibit 13.

RESPONSE:

These Defendants admit that Clint Pharmaceuticals originally invoiced the June 9, 2011, order at $8.95 per vial, but Clint Pharmaceuticals later corrected the price to $6.49 per vial for that order. STOPNC paid $6.49 per vial of MPA for the June 9, 2011, order from Clint Pharmaceuticals. These Defendants deny that Exhibit 13 is the correct invoice for the June 9, 2011, order. The correct invoice is Bates number STOPNC_0163 of Exhibit 27 to these Requests for Admissions.

81. Admit that Saint Thomas Neurosurgical was not willing to pay $8.95 per vial of MPA from Clint Pharmaceuticals if it could be procured at a lower price from NECC.

RESPONSE:

Denied. Additionally, these Defendants object to this Request for Admission and the explanation required by the corresponding Interrogatory on the grounds that they are unreasonably cumulative, duplicative, and the information sought can be obtained from some other source that is more convenient, less burdensome, and less expensive. FRCP 26(b)(2)(C)(i). STOPNC has explained the decision to purchase MPA from NECC in its Responses to Interrogatories in *Reed v. STOPNC et al.*, Case No. 13C417, *May v. STOPNC, et al.*, Case No. 13C606, *Parman v. STOPNC, et al.*, Case No. 13C1005, and/or *Neely v. STOPNC, et al.*, Case No. 13C1876, Fifth Circuit Court for Davidson County, Tennessee. The Plaintiffs from these four state court actions voluntarily dismissed the suits, refiled them in federal court, and are now part of the MDL. The Plaintiffs have this information. This Request for Admission is duplicative.

82. Admit that on June 10, 2011, Ms. Schamberg on behalf of Saint Thomas Neurosurgical emailed an NECC sales representative indicating that if NECC would guarantee a price for MPA of $6.50 per 80mg vial, Saint Thomas Neurosurgical would be willing to do business with NECC. (See Exhibit 12).

RESPONSE:

These Defendants admit that Ms. Schamberg emailed the NECC sales rep on June 10, 2011, stating that if NECC was still offering MPA at $6.50 per vial, which was comparable to the previous cost to the clinic, she was willing to do business with NECC.

83. Admit that after NECC indicated its willingness to sell Saint Thomas Neurosurgical MPA for $6.50 per 1mL 80mg vial, Ms. Schamberg obtained approval from Dr. Culclasure to begin ordering from NECC.

RESPONSE:

These Defendants admit that Ms. Schamberg discussed purchasing MPA from NECC with Dr. Culclasure, and he approved the purchase.

84. Admit that both Ms. Schamberg and Dr. Culclasure approved the purchases of MPA from NECC.

RESPONSE:

These Defendants admit that Dr. Culclasure and Ms. Schamberg both approved the purchase of MPA from NECC. These Defendants deny that both Dr. Culclasure and Ms. Schamberg directly approved each individual purchase of MPA from NECC.

85. Admit that Saint Thomas Neurosurgical placed its first order with NECC on or about June 10, 2011. That order consisted of 500 1mL 80 mg vials of MPA and 200 2mL 80 mg vials of MPA.

RESPONSE:

These Defendants admit that STOPNC placed its first order from NECC on either June 10, 2011, or June 14, 2011.[5] These Defendants admit that the order consisted of 500 one (1) mL 80 mg vials of MPA and 200 two (2) mL 80 mg vials of MPA.

86. Admit that a true and correct copy of the Prescription Order Form referenced in the preceding request reflecting Saint Thomas Neurosurgical's first order with NECC is attached as Exhibit 14.

RESPONSE:

Admitted.

[5] The date on the fax coversheet for the first order suggests that there may have been an issue with the transmission of the order on June 10, 2011 necessitating resending the order on June 14, 2011. The coversheet is Bates number STOPNC_0093 of Exhibit 27 to these Requests for Admissions.

87. Admit that the June 2011 order form attached as Exhibit 14 did not contain any patient names despite the fact that the order form included a column for that information.

RESPONSE:

These Defendants admit that the order form did not contain patient names and that the form includes a column for patient names.

88. Admit that as evidenced by Dr. John Culclasure's name/signature on the June 2011 order form attached as Exhibit 14, Dr. Culclasure was aware of and approved the purchase of MPA from NECC.

RESPONSE:

These Defendants deny that Dr. Culclasure personally signed or wrote his name on the June 2011 order form submitted to NECC. These Defendants admit that Dr. Culclasure approved the purchase of MPA from NECC.

89. Admit that NECC sent invoices to Saint Thomas Neurosurgical evidencing five separate purchases by Saint Thomas Neurosurgical of five-hundred 80 mg. vials of MPA as reflected in invoices dated June 6, 2012; June 26, 2012; July 25, 2012; August 13, 2012; and August 31, 2012. A true and correct copy of those invoices is attached as Exhibit 15.

RESPONSE:

Admitted.

90. Admit that Saint Thomas Neurosurgical purchased 2,500 vials of MPA from NECC during the time period June through August 2012.

RESPONSE:

These Defendants admit that STOPNC purchased 2,500 vials of MPA from NECC from June through August 2012.

91. Admit that in early to mid-2012, an NECC representative informed Ms. Schamberg that NECC needed Saint Thomas Neurosurgical to submit a list of patients with each order in order to comply with Massachusetts Board of Pharmacy requirements.

RESPONSE:

Admitted.

92. Admit that Ms. Schamberg told the NECC representative that she could not predict which patients would receive MPA. The NECC representative indicated that any list of patient names would suffice.

RESPONSE:

These Defendants admit that Ms. Schamberg told the NECC rep that STOPNC would not be able to predict with certainty each and every patient who would actually receive the MPA. These Defendants admit that the representative stated that NECC just needed a list of patient names.

93. Admit that a true and correct copy of a Saint Thomas Neurosurgical interrogatory response discussing its communications with NECC is attached as Exhibit 16.

RESPONSE:

Admitted in part and denied in part. Exhibit 16 does not include STOPNC's Supplemental Response to the Interrogatory discussing STOPNC's communications with NECC, which was provided to the Plaintiffs on or about March 28, 2013.

94. Admit that Saint Thomas Neurosurgical provided NECC with lists of patients' names (including Mickey Mouse) with its order(s) for MPA from NECC. Saint Thomas Neurosurgical provided those patient lists to NECC even though the patients on those lists did not necessarily receive MPA.

RESPONSE:

Denied as stated. As NECC requested, STOPNC provided NECC with a list of patients from its daily schedule. STOPNC regularly used "Mickey Mouse" and "Minnie Mouse" as placeholders in the schedule to avoid booking patients at times when no physician was available. STOPNC did this *prior to* its dealings with NECC. STOPNC generally did not provide to NECC patient lists that included such placeholders. STOPNC redacted the placeholders prior to sending the lists. But, these Defendants admit that one schedule provided to NECC included an unredacted "Mickey Mouse" placeholder. These Defendants admit that patients on the lists sent to NECC may not have received MPA from the orders for which the lists were submitted.

95. Admit that a redacted copy of a list of patient names submitted to NECC by Saint Thomas Neurosurgical showing the name "Mickey Mouse" is attached as Exhibit 17.

RESPONSE:

Admitted.

96. Admit that the Tennessee Department of Health and the United States Centers for Disease Control and Prevention ("CDC") began investigating a fungal meningitis outbreak in September 2012.

RESPONSE:

These Defendants admit that the Tennessee Department of Health and the CDC began investigating a cluster of meningitis cases in September 2012. These Defendants deny that the volume of cases in September 2012 rose to the level of an "outbreak" or that a definitive determination had been reached that the disease state was fungal meningitis in September 2012.

97. Admit that several patients of Saint Thomas Neurosurgical were diagnosed with fungal meningitis after being injected with MPA procured from NECC.

RESPONSE:

Admitted.

98. Admit that on September 20, 2012, Saint Thomas Neurosurgical closed because of the fungal meningitis outbreak.

RESPONSE:

Denied as stated. On September 20, 2012, STOPNC closed because one patient who had received epidural steroid injections at STOPNC had been diagnosed with fungal meningitis at Vanderbilt University Medical Center, and two additional patients who had received epidural steroid injections at STOPNC had been admitted at St. Thomas Hospital with symptoms of meningitis.

99. Admit that attached as Exhibit 18 is a true and correct copy of information from the CDC website located at http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html.

RESPONSE:

Admitted.

100. Admit that according to the CDC, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml on September 26, 2012:

- Lot #05212012@68, BUD 11/17/2012;
- Lot #06292012@26, BUD 12/26/2012; and
- Lot #08102012@51, BUD 2/6/2013.

RESPONSE:

Admitted.

101. Admit that according to the CDC, Saint Thomas Neurosurgical received MPA from NECC that was from one or more of the recalled lots.

RESPONSE:

Admitted.

102. Admit that attached as Exhibit 19 is a true and correct copy of the FDA Form 483 for New England Compounding Center issued on October 26, 2012.

RESPONSE:

Admitted.

103. Admit that the FDA analyzed 50 vials from lot 08102012@51 (one of the three lots originally recalled by NECC).

RESPONSE:

These Defendants admit that Exhibit 19 states that the FDA analyzed 50 vials of FDA Sample #693965, consisting of methylprednisolone acetate (PF) 80mg/mL, 1mL filled vials, from lot 08102012@51 collected from NECC.

104. Admit that the FDA confirmed the presence of viable microbial growth in 50 out of 50 vials tested from lot 08102012@51.

RESPONSE:

These Defendants admit that Exhibit 19 states that the FDA analyzed 50 full vials of FDA Sample #693965, consisting of methylprednisolone acetate (PF) 80mg/mL, 1mL vials, from lot 08102012@51 collected from NECC and confirmed the presence of viable microbial growth in all 50 of the vials tested.

105. Admit that attached as Exhibit 20 is a true and correct copy of CDC laboratory confirmed results from three NECC MPA lots recalled on September 26, 2012.

RESPONSE:

These Defendants admit that Exhibit 20 is a true and correct copy of CDC laboratory confirmed results from three of NECC's methylprednisolone acetate (PF) lots recalled on September 26, 2012, as summarized and reported on the CDC website. These Defendants deny that Exhibit 20 contains the actual laboratory data.

106. Admit that the CDC isolated *Exserohilum rostratum* in two of the three lots of MPA originally recalled from NECC.

RESPONSE:

These Defendants admit that Exhibit 20 states that tests at the CDC and FDA confirmed the presence of *Exserohilum rostratum* in unopened vials from two of the three recalled lots.

107. Admit that according to the CDC, *Exserohilum rostratum* is the same fungus as the one found in laboratory-confirmed cases of human infection.

RESPONSE:

Denied as stated. The CDC reported identifying twelve (12) different fungi in case patients, in addition to *Exserohilum rostratum*. These Defendants admit that the CDC reported that *Exserohilum rostratum* was the "predominant fungal infection in this outbreak."

108. Admit that epidural steroid injections administered to various patients at Saint Thomas Neurosurgical were contaminated with fungus.

RESPONSE:

These Defendants have made a reasonable inquiry and the information known and readily obtainable is insufficient to permit an admission or denial. The empty vials of MPA used during patients' procedures were destroyed following their procedures in accordance with generally-accepted practices for disposing of medical waste. These Defendants admit that patients who received injections at STOPNC had cultures positive for fungus.

109. Admit that epidural steroid injections administered to various patients at Saint Thomas Neurosurgical caused them to contract fungal meningitis. That disease caused some patients to die, and it sickened others.

RESPONSE:

Objection. This Request for Admission seeks an expert opinion and/or medical causation testimony before the Court has set a deadline for disclosing experts.

Subject to and without waiving said objection, this Request for Admission is denied as stated. Contaminated medication received by STOPNC from NECC caused patients to contract fungal meningitis, not the healthcare services provided by physicians at STOPNC. These Defendants admit that the disease caused some patients to die and sickened others.

110. Admit that fungal meningitis caused some Saint Thomas Neurosurgical patients to die.

RESPONSE:

Objection. This Request for Admission seeks an expert opinion and/or medical causation testimony before the Court has set a deadline for disclosing experts.

Subject to and without waiving said objection, these Defendants admit, based upon information and belief, that fungal meningitis caused some STOPNC patients to die.

111. Admit that fungal meningitis sickened some Saint Thomas Neurosurgical patients.

RESPONSE:

Objection. This Request for Admission seeks an expert opinion and/or medical causation testimony before the Court has set a deadline for disclosing experts.

Subject to and without waiving said objection, these Defendants admit that fungal meningitis sickened some STOPNC patients.

112. Admit that no facts suggest that patients who contracted fungal meningitis after receiving epidural steroid injections at Saint Thomas Neurosurgical administered during July, August and/or September of 2012 contracted that disease from any source other than those epidural steroid injections.

RESPONSE:

Objection. This Request for Admission seeks an expert opinion and/or medical causation testimony before the Court has set a deadline for disclosing experts.

Subject to and without waiving said objection, these Defendants admit, based upon information and belief, that some patients who contracted fungal meningitis after receiving epidural steroid injections at STOPNC administered during July, August, and/or September of 2012 contracted the fungal meningitis as a result of receiving contaminated medication from NECC during their treatment at STOPNC. However, at this point, full investigation of the pathology of each individual infection has not been completed.

113. Admit that attached as Exhibit 21 is a true and correct copy of a print-out of an archived version of Howell Allen Clinic's website as it existed on June 18, 2012, accessed at http://web.archive.org/web/20120618174929/http://howellallen.com/clinic/locations.php.

RESPONSE:

Admitted.

114. Admit that as reflected on Exhibit 21, Howell Allen Clinic listed "St. Thomas Outpatient Neurosurgical Center" as one of its clinic locations as recently as June 2012.

RESPONSE:

Admitted.

115. Admit that as reflected on Exhibit 21, Howell Allen Clinic listed "St. Thomas Office" as one of its clinic locations as recently as June 2012.

RESPONSE:

Admitted.

116. Admit that attached as Exhibit 22 is a true and correct copy of a print-out of an archived version of Howell Allen Clinic's website as it existed on June 22, 2012, accessed at http://web.archive.org/web/20120622063123/http://howellallen.com/stThomas_outpatient.htm.

RESPONSE:

Admitted.

117. Admit that as reflected on Exhibit 22, Howell Allen Clinic described Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Neurosurgical") in part as follows:

> "Howell Allen Clinic's St. Thomas Outpatient Neurosurgical Center provides efficient and professional ambulatory care to have you in, out and on your way to recovery in no time.
>
> . . .
>
> Our physicians and nurses will make every effort to ensure that you are comfortable during this time."

RESPONSE:

These Defendants admit that the website included the quoted language but deny that it is the entire section of text.

118. Admit that attached as Exhibit 23 is a true and correct copy of a print-out of Howell Allen Clinic's website as it existed on February 8, 2013, located at http://howellallen.com/locations.com.

RESPONSE:

These Defendants do not know how the Howell Allen Clinic website appeared on February 8, 2013, and after reasonable inquiry, that information is not readily obtainable by these Defendants. Thus, this request as stated is neither admitted nor denied. Exhibit 23 appears similar to the Howell Allen Clinic website.

119. Admit that Howell Allen Clinic removed from its "office locations" webpage, all references to St. Thomas Outpatient Neurosurgical Center after the recent fungal meningitis outbreak.

RESPONSE:

These Defendants admit that the Howell Allen website no longer lists STOPNC as a location.

120. Admit that the webpage (and any corresponding link) reflected on Exhibit 22 was removed from Howell Allen Clinic's website after the recent fungal meningitis outbreak.

RESPONSE:

Admitted.

121. Admit that attached as Exhibit 24 is a true and correct copy of a brochure provided to patients by Howell Allen Clinic.

RESPONSE:

Admitted.

122. Admit that as reflected on Exhibit 24, Howell Allen Clinic listed St. Thomas Outpatient Neurosurgical Center as one of its office locations.

RESPONSE:

Admitted.

123. Admit that attached as Exhibit 25 is a true and correct copy of a billing statement from Saint Thomas Neurosurgical.

RESPONSE:

Denied.

124. Admit that the telephone number reflected on Saint Thomas Neurosurgical's billing statement (Exhibit 25) is the same telephone number that appears on Howell Allen Clinic's website.

RESPONSE:

Denied.

125. Admit that attached as Exhibit 26 is a true and correct copy of a billing statement from Howell Allen Clinic.

RESPONSE:

These Defendants admit that Exhibit 26 appears to be a true and correct copy of a billing statement from Howell Allen with the patient's name and address redacted.

126. Admit that attached as Exhibit 27 is a CD containing true and correct copies of documents produced by Saint Thomas Outpatient Neurosurgical Center, LLC in the action styled: Wayne A. Reed, individually and as husband and next of kin of decedent, Diana E. Reed v. Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic a Professional Corporation, Saint Thomas Network, Saint Thomas Health, and St. Thomas Hospital; Davidson County Circuit Court No. 13C417. Those documents are bates labeled STOPNC_0001 – STOPNC_0313; STOPNC_0320 – STOPNC_0328; STOPNC_0335 – 0531; and STOPNC_0533 - 0749.

RESPONSE:

Objection. These Defendants object to this Request for Admission on the grounds that it is unduly burdensome to compare the documents contained in Exhibit 27 to the documents produced in *Reed v. STOPNC, et al.*, Davidson County Circuit Court No. 13C417 to confirm that they are the same documents. Additionally, these Defendants deny that Exhibit 27 was attached to the Plaintiffs' Requests for Admissions as a separate CD. Subject to and without waiving said objections, these Defendants admit that they answered extensive discovery in state court cases and that the Plaintiffs here are in possession of those documents. These Defendants do not dispute the authenticity of the documents they produced.

127. Admit that attached as Exhibit 28 is a CD containing true and correct copies of photographs produced by Saint Thomas Outpatient Neurosurgical Center, LLC in the action styled: Wayne A. Reed, individually and as husband and next of kin of decedent, Diana E. Reed v. Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic a Professional Corporation, Saint Thomas Network, Saint Thomas Health, and St. Thomas Hospital; Davidson County Circuit Court No. 13C417. Those photographs are bates labeled STOPNC_0750 – STOPNC_0794.

RESPONSE:

Objection. These Defendants object to this Request for Admission on the grounds that it is unduly burdensome to compare the photographs contained in Exhibit 28 to the documents produced in *Reed v. STOPNC, et al.*, Davidson County Circuit Court No. 13C417 to confirm that they are the same photographs. Additionally, these Defendants deny that Exhibit 28 was attached to the Plaintiffs' Requests for Admissions as a separate CD. Subject to and without waiving said objections, these Defendants admit that they answered extensive discovery in state court cases and that the Plaintiffs here are in possession of those documents. These Defendants do not dispute the authenticity of the documents they produced.

128. Admit that attached as Exhibit 29 is a CD containing true and correct copies of documents produced by Howell Allen Clinic in the action styled: Wayne A. Reed, individually and as husband and next of kin of decedent, Diana E. Reed v. Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic a Professional Corporation, Saint Thomas Network, Saint Thomas Health, and St. Thomas Hospital; Davidson County Circuit Court No. 13C417. Those documents are bates labeled HAC_005 – HAC_029.

RESPONSE:

Objection. These Defendants object to this Request for Admission on the grounds that it is unduly burdensome to compare the documents contained in Exhibit 29 to the documents produced in *Reed v. STOPNC, et al.*, Davidson County Circuit Court No. 13C417 to confirm that they are the same documents. Additionally, these Defendants deny that Exhibit 29 was attached to the Plaintiffs' Requests for Admissions as a separate CD. Subject to and without waiving said objections, these Defendants admit that they answered extensive discovery in state court cases and that the Plaintiffs here are in possession of those documents. These Defendants do not dispute the authenticity of the documents they produced.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

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Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice.*

CERTIFICATE OF SERVICE

I hereby certify that on the 20th day of October, 2014, a true and accurate copy of the foregoing was served on the PSC by hand-delivery and on the other parties below by serving a notice indicating that the PSC will upload the responses to the discovery repository in the MDL:

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/s/ Chris J. Tardio
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